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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/535,005	11/18/2005	David Neil Cooper	348-077	2635

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EXAMINER	
MACFARLANE, STACEY NEE	
ART UNIT	**PAPER NUMBER**
1649	
MAIL DATE	**DELIVERY MODE**
08/14/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/535,005	COOPER ET AL.	
	Examiner	Art Unit	
	Stacey MacFarlane	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 November 2005*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *29-140* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *29-140* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions that are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 29, 31, 33, 35, 64, 66, 75, 77, 79 and 81, drawn to an isolated variant of the human growth hormone nucleic acid molecule comprising the substitution +1491 C→G, and a vector and host cell comprising said nucleic acid.

Group 2, claim(s) 30, 32, 34, 65, 67, 76, 78, 80, 82, and 139 drawn to an isolated variant of the growth hormone nucleic acid molecule, and a vector and host cells comprising said nucleic acid.

Group 3, claim(s) 36 and 38, drawn to an isolated polypeptide encoded by the variant of the human growth hormone nucleic acid molecule comprising the substitution +1491 C→G.

Group 4, claim(s) 37 and 140, drawn to an isolated polypeptide encoded by the variant of the growth hormone nucleic acid molecule.

Group 5, claim(s) 39, drawn to an isolated polypeptide which is a variant of the growth hormone protein, GH, and which includes the substitution Ile179Met.

Group 6, claim(s) 40 and 41, drawn to a screening method for screening an individual suspected of having dysfunctional GH, which comprises obtaining and sequencing DNA.

Group 7, claim(s) 42, drawn to a screening method for screening an individual suspected of having dysfunctional GH, which comprises obtaining and sequencing a polypeptide.

Group 8, claim(s) 43, drawn to a kit suitable for carrying out the screening method of Group 6.

Group 9, claim(s) 44, drawn to a kit suitable for carrying out the screening method of Group 7.

Group 10, claim(s) 45, drawn to an oligonucleotide for use in the method of Group 6.

Group 11, claim(s) 46, drawn to an oligonucleotide for use in the method of Group 7.

Group 12, claim(s) 47, drawn to an oligonucleotide suitable for use in the kit of Group 8.

Group 13, claim(s) 48, drawn to an oligonucleotide suitable for use in the kit of Group 9.

Group 14, claim(s) 49-53, 68-72, 111-115, 118-122, 125-129, and 132-136, drawn to an isolated growth hormone polypeptide containing a Ile179Met substitution.

Group 15, claim(s) 54-55, 73-74, 116-117, 123-124, 130-131, and 137-138, drawn to isolated growth hormone polypeptide or protein, which is characterized by possessing a reduced ability to activate the MAP kinase pathway.

Group 16, claim(s) 56, drawn to a screening method for screening an individual suspected of having dysfunctional GH comprising obtaining a polypeptide and examining receptor-mediated MAPK signaling.

Group 17, claim(s) 57-61, drawn to an antibody specific for the isolated growth hormone polypeptide which is a variant of the growth hormone protein, GH, and which includes the substitution Ile179Met.

Group 18, claim(s) 62-63, drawn to an antibody specific for the isolated growth hormone polypeptide, which is characterized by possessing a reduced ability to activate the MAP kinase pathway.

Group 19, claim(s) 83-87, 90-94, 97-101, 104-108, drawn to a process for preparing the isolated growth hormone polypeptide containing an Ile179Met substitution.

Group 20, claim(s) 88-89, 95-96, 102-103, 109-110, drawn to a process for preparing an isolated growth hormone polypeptide or protein, which is characterized by possessing a reduced ability to activate the MAP kinase pathway.

2. The inventions listed as Groups 1-20 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the single general

inventive concept that permeates the groups is mutations in growth hormone nucleic acid or polypeptide. The expression "special technical feature" is defined in Rule 13.2 as meaning those technical features that define a contribution which each of the inventions makes over the prior art. Whether a particular feature makes a contribution over the prior art, is considered with respect to novelty and inventive step. In the instant application, the mutations in growth hormone nucleic acid and or protein, do not constitute a contribution over the prior art. The following reference teaches gene mutations in the human GH1 gene, resulting in loss of function (Takahashi et al. Journal of Clinical Investigation, 100:1159-1165, published September 1997). The prior art recites the common technical feature of Groups 1-20, thus, there is no special technical feature over the prior art and the application lacks Unity of Invention under PCT Rule 13.1.

Additionally, the PCT rules provide for the examination of the first claimed product, the first claimed method of making that product, and the first claimed method of using that product in one application, but do not provide for the examination of multiple products or unrelated methods. For example, the antigenic product and antibody differ in structure, biological function, and capable uses. The methods use different steps and different reagents corresponding to the distinct technical features, and exhibit different effects, functions and outcomes. For example, the special technical feature of Group 3 is an isolated polypeptide encoded by a variant of the human growth hormone nucleic acid molecule comprising the substitution +1491 C→G, whereas Group 15 is drawn

more broadly to any isolated growth hormone polypeptide or protein, which is characterized by possessing a reduced ability to activate the MAP kinase pathway.

Accordingly, Groups 1-20 are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, recognized divergent subject matter and non-coextensive literature searches, which also includes searching different electronic databases, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder.

All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacey MacFarlane whose telephone number is (571) 270-3057. The examiner can normally be reached on Monday-Thursday 6:30AM-4:00 PM & ALT. Fridays, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Stacey MacFarlane
Examiner
Art Unit 1649

SNM

OLGA N. CHERNYSHEV, PH.D.
PRIMARY EXAMINER